LETTERS

Dietary Supplements Have Not Changed Profession's Code of Ethics

To the Editor. I read with disappointment the article by Pray in the *AJPE* supplement on nonprescription medications and self-care.[1] Far from taking the evidence-based approach the author extols, the article cherry-picks examples to suit his conclusion that the current pharmacy code of ethics approved by most national and state pharmacy practitioner associations has been weakened and that many organizations and publishers have diluted their standards in the wake of passage and implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA).

In the case of the American Pharmacists Association (APhA), nothing could be further from the truth. Ignored is passage of a policy on homeopathy—and the need for "adequate, well-designed scientific studies" of it—by the 2002 APhA House of Delegates[2] and publication of the literature-based Alternative Medicine Corner in every issue of *APhA DrugInfoLine* since its inception in January 2000. In the author's systematic review of the literature, did he miss the peer-reviewed articles in the *Journal of the American Pharmacists Association* reviewing published sources of reference books on botanical dietary supplements[3] and the effects of zinc on the common cold virus?[4] APhA's news magazine, *Pharmacy Today*, has published a column on Alternative/Integrative Medicine since January 2004, yet only those articles that could be used to fit the author's premise were included for readers' consideration. Unreviewed completely were the more than 1,000 daily news stories posted on www.pharmacist.com since 2002, including those reporting the results of randomized, controlled trials of dietary supplements, usually provided to members within hours of the studies' release on journal Web sites. Advertising is also criticized by Pray, even though these promotions met the standards of the Food and Drug Administration and/or the Federal Trade Commission and arbitrary rejection of legally compliant advertising on the part of APhA could be construed as restraint of trade.

The author, who discloses his own financial interests in 2 competing textbooks, is particularly critical of the inclusion of chapters on dietary supplements and homeopathy in APhA's *Handbook of Nonprescription Drugs*. For the editors of this work to have ignored the passage of DSHEA and have taken an ostrich approach to the burgeoning use of integrative medicine by the increasingly diverse American population would have been unconscionable. In the *Handbook*, respected editors and authors objectively present the uses people are making of dietary supplements as well as the evidence supporting—or failing to support—the uses thereof.

In short, APhA's stance on dietary supplements has not changed, and in fact, our policy on one of the more controversial interventions—homeopathy—was affirmed by our House just 5 years ago. We strongly advocate an evidence basis to the practice of medicine and pharmacy. In fact, APhA is publishing a book that I wrote with a colleague, *Evidence-Based Pharmacotherapy*. I would hope that in the future unbalanced papers such as this one will not find their way into the pages of this *Journal*, but instead authors will conduct systematic reviews of available literature, assess its content objectively, and reach sound conclusions that are truly supported by the available evidence.

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Complementary and Alternative Medicine

To the Editor. Since 2001, I have been one of the authors of the chapter on herbal medicines in the 13th, 14th, and 15th edition of the *Handbook of Nonprescription Drugs* by the American Pharmacists Association. In the fall 2006, I became the section editor for the upcoming 16th edition of the *Handbook*. In these roles as well as an educator of students, health professionals, and consumers and as a pharmacist in family medicine for 20 years, I want to share a few reflections on the recent article by Steven Pray, PhD, in this *Journal*.[1]

My interest in complementary and alternative medicine (CAM) developed largely by accident. In 1994, I was elected chair of the Ambulatory Care Practice and Research Network of the American College of Clinical

Pharmacy. In discussing ideas for an upcoming educational program, several colleagues were outraged that we were even considering CAM as a potential topic. One individual stated that he absolutely did not want his patients using CAM. I was struck not only by the paternalistic attitude but also by the apparent belief on the part of some individuals that to discuss CAM was to promote or endorse it in some way. In the intervening years, I've had the opportunity to contribute to the development on a white paper on pharmacists and herbal products, serve on grant review panels for the National Center for Complementary and Alternative Medicine, participate on a state panel regarding the potential need for licensing of naturopaths, as well as teach an evidence-based approach to CAM to pharmacy, nursing, and medical students and health professionals.

We must recognize that much of medicine, pharmacy, and health care in general is not evidence-based, despite our best intentions. The use of calcium channel blockers in hypertension and after myocardial infarction is just one example. Since their initial introduction, the use of calcium channel blockers has been common yet the actual evidence of their benefit over established proven therapies is quite limited. We have treated patients for many years based on theories, not on actual evidence. Numerous other examples in acute and chronic diseases could be cited, including those in otitis media and diabetes mellitus. The management of many diseases in older adults is similarly not based on evidence; a colleague of mine refers to the care of older adults as "evidence *biased*." While many dietary supplements are unproven, the truth is that many prescription and nonprescription drugs are as well if we use the true standard of trying to decrease morbidity and mortality and not simply treating a surrogate marker of the disease.

We must recognize that from the patient's perspective healthcare has changed dramatically within the post-hippie timeframe explored in the Pray article. People have far greater access to information on health, drugs and dietary supplements, an effect magnified by the Internet. Individuals increasingly have access to their online medical records as part of patient-centered care. Many people want to make their own decisions, while others struggle with even knowing what questions to ask of their provider. One of the greatest public health roles that pharmacists can assume is to be the knowledgeable, unbiased source of information regarding prescription drugs, nonprescription medications, and dietary supplements. If pharmacists fail to assess the potential risks and benefits of dietary supplements—including what the evidence shows or doesn't show—the clerk at the local health food store will certainly know the most trivial factoid from an in vitro study yet fail to appreciate the larger issues in managing a given disease.

We must recognize the influence of corporations on pharmacy and pharmacists. Many pharmacists are employees instead of owners. As employees, many pharmacists no longer make the decision regarding what is or is not stocked in a pharmacy. Pray's article focuses on pharmacists making decisions about products to stock based on the profit motive and on interactions at booths at national meetings. He fails to address the fact that many chain pharmacies continue to sell cigarettes, the single most important risk to the health of the American public.

I've highlighted these issues because Pray states that "the growing acceptance of unproven medications by pharmacists may be due to the nonprescription textbook that faculty members choose for their students' use." As the author of the botanical medicines chapter, I spent considerable effort in being balanced in assessing and summarizing the clinical evidence, adverse reactions, drug interactions, and product issues. A careful review of the last 3 editions reveals a thorough integration of research and clinical issues that emphasize patient safety including when self-care with natural products is or is not appropriate. A delicate balance exists in respecting and understanding individual beliefs and promoting an evidence-based approach to caring for patients. This is just one of the many challenges that confront community pharmacists, day in and day out.

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Editor's Note: Dr. Steven Pray submitted a response to the letters by Drs. Hume and Posey; however, it is not published here by decision of the Editor.

OSHA Is Not a City in Wisconsin

To the Editor: Schools and colleges of pharmacy in the United States are experiencing unprecedented growth. During the past 15 years, dozens of new schools and colleges of pharmacy have opened their doors in an attempt to ameliorate the pharmacist shortage. Moreover an additional 10 universities and colleges are expected to open pharmacy schools by 2010.[1] Many of these new or

proposed pharmacy schools reside in small liberal arts universities with little infrastructure in place to accommodate a pharmacy school. One area of consideration that is often not addressed is issues related to complying with the Occupational Safety and Health Administration (OSHA) standards and regulations.

OSHA has the responsibility to protect and assure the safety and health of America's workers by setting, and enforcing standards while encouraging continual improvement in workplace safety and health.[2] Academic administrators often do not realize that colleges, universities, and professional schools must comply with state and/or federal OSHA standards relating to safety in teaching or research laboratories and exposure to blood borne products or bodily fluids. Federal OSHA standards only apply to relationships established between employers and employees and do not extend federal protection to students. However, 22 states have OSHA approved plans that may mandate safety protection and training for students. Because of medical/legal considerations, most academic institutions have implemented policies to include students in OSHA compliance plans.

Violation of OSHA standards can be costly to an institution. A minor violation that has a direct relationship to safety or could cause physical harm carries a maximum penalty of $7000. If the employer knows that a circumstance or operation constitutes a hazardous condition and makes no reasonable attempt to eliminate it, more severe penalties are imposed with maximum fines of $70,000.[2] Because of the complexity of the OSHA standards, multiple violations of a single standard are the rule. Where willful violations result in serious injury, disease, or death, cases are referred to the Department of Justice for possible criminal prosecution.[2]

If the School of Pharmacy is not included in a college or university OSHA master plans, administrators must develop, implement, and maintain detailed written plans that comply with OSHA standards. These plans, which are legal covenants between the institution and the government, describe the methods used to protect and train workers. The following paragraphs have been excerpted from the standards that are relevant to Schools of Pharmacy.

Occupational exposure to hazardous chemicals in laboratories- 29CFR -1910.1450[3] Compliance requires a Chemical Hygiene Plan (CHP) based on the assumption that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals, and that a different approach than that found in OSHA's substance specific health standards is warranted to protect workers. This standard applies to all laboratories that use hazardous chemicals in accordance with the definitions of laboratory use and laboratory scale provided in the standard. By definition, a hazardous chemical is any chemical that is a potential/actual physical health hazard. For laboratories covered by this standard, there is an obligation to maintain employee exposures at or below the permissible exposure limits (PELs). The CHP must include the necessary work practices, procedures and policies to ensure that employees are protected from all potentially hazardous chemicals used or stored in their work area. Among other requirements, the standard provides for employee training, medical consultation and examination, hazard identification, respirator use (if necessary), and record keeping. To the extent possible, the standard allows a large measure of flexibility in compliance methods.

Hazardous Communication Standard (HCS) 29CFR 1910.1200[4] The HCS standard is based on the concept that employees have both a need and a right to know the hazards and identities of the chemicals they are exposed to when working. It is intended to insure that employees know what protective measures are available to prevent adverse effects from occurring. The written HCS plan has several critical components which include: identification of persons responsible for implementation of the plan, a current chemical inventory, procedures for labeling of chemicals in the laboratory, procedures for obtaining and maintaining Material Safety Data Sheets (MSDSs) and methods used to train employees and students. Training plans must be in sufficient detail so that OSHA compliance officers can make a determination whether or not a good faith effort is being made to train employees.

Bloodborne Pathogens Standard 29 CFR 1910.1030[5] If there is possibility of exposure to blood or other possibly infectious material (OPIM), institutions must have an Exposure Control Plan (ECP) that is designed to protect workers or minimize exposure to bloodborne pathogens. Using the OSHA definition, occupational exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of normal duties. In the document, the employer must describe methods used to identify jobs, job classifications, or circumstances in which employees or students may have exposure. Individuals with potential exposure must be offered Hepatitis B vaccination (at no cost to the employee). If the subject has received a previous hepatitis vaccination, immunity must be demonstrable by seroconversion. The document also must describe the universal precautions undertaken to protect the individuals and the method used to dispose of contaminated material. In addition, a written post exposure protocol for medical evaluation, treatment and counseling

must be an integral part of the document. Annual blood borne pathogen training, which meets OSHA requirements, also must be provided and documented by the employer. In 2001, in response to the NeedleStick Safety and Prevention Act, the Bloodborne Pathogens Standard was revised.[6] The revised standard requires annual consideration and implementation of appropriate commercially available and effectively safer medical devices designed to eliminate or minimize occupational exposure. Employers also must solicit input from non-managerial employees in the identification, evaluation, and selection of effective engineering and work practice controls. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.

Compliance with OSHA standards is not without cost. Additional personnel may be required for the development, implementation and maintenance of all written plans and documents required for compliance. Monetary resources also must be redirected for vaccinations, seroconversion studies, medical monitoring, and record keeping using the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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